

US009439802B2

(12) **United States Patent**
Wagner

(10) **Patent No.:** **US 9,439,802 B2**

(45) **Date of Patent:** ***Sep. 13, 2016**

(54) **ORAL DEVICES, KITS AND METHODS FOR REDUCING SLEEP APNEA, SNORING, AND/OR NASAL DRAINAGE**

(71) Applicant: **W. R. Wagner Family Limited Partnership**, Houston, TX (US)

(72) Inventor: **Wayne R. Wagner**, The Woodlands, TX (US)

(73) Assignee: **W.R. WAGNER FAMILY LIMITED PARTNERSHIP**, Houston, TX (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/852,768**

(22) Filed: **Sep. 14, 2015**

(65) **Prior Publication Data**
US 2015/0374536 A1 Dec. 31, 2015

Related U.S. Application Data
(63) Continuation of application No. 13/456,682, filed on Apr. 26, 2012, now Pat. No. 9,144,512.

(51) **Int. Cl.**
A61F 5/56 (2006.01)
A61C 7/00 (2006.01)
A61C 7/36 (2006.01)

(52) **U.S. Cl.**
CPC **A61F 5/566** (2013.01); **A61C 7/006** (2013.01); **A61C 7/36** (2013.01)

(58) **Field of Classification Search**
CPC A61F 5/566; A61F 5/56; A61F 5/50; A61F 5/58; A63B 71/085; A63B 2071/088; A63B 2208/12; A61B 13/00; A61C 5/14
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,132,647 A 5/1964 Giuseppe
3,434,470 A 3/1969 Strickland

(Continued)

FOREIGN PATENT DOCUMENTS

EP 1203570 B1 11/2001
EP 1205157 5/2002

(Continued)

OTHER PUBLICATIONS

Landers, SJ, "Link strengthened between sleep apnea and mortality risk", *amednews*, Sep. 1, 2008.

(Continued)

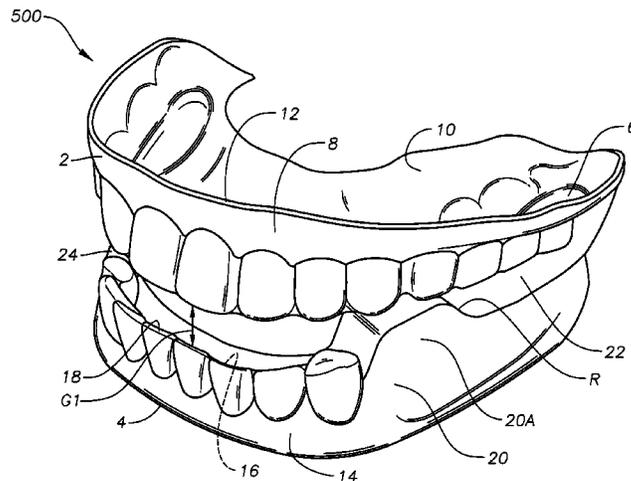
Primary Examiner — Ophelia A Hawthorne

(74) *Attorney, Agent, or Firm* — Jeffrey L. Wendt; The Wendt Firm, P.C.

(57) **ABSTRACT**

Apparatus for reducing obstructive sleep apnea, snoring and/or nasal drainage. One apparatus includes an upper member fitting the interior and exterior surfaces of a user's upper dentition, and a lower member fitting similarly adjacent a user's lower dentition. The lower member includes molar extensions projecting away from the lower member. The upper member includes upper molar extensions projecting away from the upper member and toward the lower molar extensions so that when the user bites or clenches, the upper right and lower right extensions impinge on one another in substantially overlapping fashion, as do the molar upper left and lower left extensions. The upper and lower members have an anterior shape to form a gap sufficient for the user's tongue to extend into the gap, and each molar extension may include a magnet. Methods of using the apparatus and kits to reduce sleep apnea, snoring, and/or nasal drainage.

7 Claims, 9 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

4,304,227 A 12/1981 Samelson
 4,396,373 A 8/1983 Dellinger
 4,531,916 A 7/1985 Scantlebury et al.
 4,676,240 A 6/1987 Gardy
 4,700,697 A 10/1987 Mundell et al.
 4,708,646 A 11/1987 Jasper
 4,715,368 A 12/1987 George
 4,901,737 A 2/1990 Toone
 5,056,534 A 10/1991 Wright
 5,117,816 A 6/1992 Shapiro et al.
 5,239,995 A 8/1993 Estes et al.
 5,499,633 A 3/1996 Fenton
 RE35,295 E 7/1996 Estes et al.
 5,570,704 A 11/1996 Buzzard et al.
 5,611,355 A 3/1997 Hilsen
 5,683,244 A 11/1997 Truax
 5,692,521 A 12/1997 Leasure-Nelson
 6,074,207 A 6/2000 Coats
 6,082,363 A 7/2000 Washburn
 6,109,265 A 8/2000 Frantz et al.
 6,213,959 B1 4/2001 Kushida
 6,427,689 B1 8/2002 Estes
 6,491,037 B1 12/2002 Mortenson
 6,505,625 B1 1/2003 Uenishi
 6,766,802 B1 7/2004 Keropian
 7,107,992 B2 9/2006 Brooks et al.
 7,178,529 B2 2/2007 Kownacki
 7,225,021 B1 5/2007 Park et al.
 7,255,110 B2 8/2007 Knudson et al.
 7,322,356 B2 1/2008 Critzer et al.
 7,451,767 B2 11/2008 Keropian
 7,540,843 B2 6/2009 De Backer
 7,607,439 B2 10/2009 Li
 7,637,262 B2 12/2009 Bailey
 7,712,468 B2 5/2010 Hargadon
 7,810,502 B1 10/2010 Nguyen et al.
 8,061,358 B2 11/2011 Smernoff
 8,215,312 B2 7/2012 Garabadian et al.
 8,257,079 B1 9/2012 Plowman
 8,272,866 B2 9/2012 Chun et al.
 8,875,713 B2 11/2014 Metz
 8,881,733 B1 11/2014 Harkins
 9,204,991 B1 12/2015 Harkins
 2001/0027793 A1 10/2001 Tielmans
 2004/0177852 A1 9/2004 Abramson
 2005/0121039 A1 6/2005 Brooks et al.
 2005/0236003 A1 10/2005 Meader
 2006/0252685 A1 11/2006 Gould
 2006/0289013 A1 12/2006 Keropian
 2007/0283967 A1 12/2007 Bailey
 2008/0060660 A1 3/2008 Nelson et al.
 2008/0173312 A1 7/2008 Peake et al.
 2008/0199824 A1 8/2008 Hargadon
 2008/0210244 A1 9/2008 Keropian
 2008/0257358 A1 10/2008 Stern et al.
 2008/0264422 A1 10/2008 Fishman
 2008/0276938 A1 11/2008 Jeppesen et al.
 2009/0036889 A1 2/2009 Callender
 2009/0056724 A1 3/2009 Keropian
 2009/0120448 A1 5/2009 Keropian
 2009/0188510 A1 7/2009 Palmer

2010/0211184 A1 8/2010 Rousseau et al.
 2010/0224197 A1 9/2010 Keropian
 2010/0300458 A1 12/2010 Stubbs et al.

FOREIGN PATENT DOCUMENTS

WO 2007134375 11/2007
 WO 2010040026 A1 4/2010
 WO 2010062952 A1 6/2010
 WO 2010093264 8/2010

OTHER PUBLICATIONS

Sleep Apnea Appliances, I Hate CPAP!, p. 1-8, downloaded from the Internet Oct. 25, 2010.
 Prehn, Ronald S., "What is a Mandibular Advancement Splint and How Does it Work?", YouTube video, uploaded to the Internet by rsprehn on Mar. 4, 2010, <http://www.youtube.com/watch?v=OWiQQF4xQZc>.
 Tomed SomnoGuard FittingHeated for 20 seconds, YouTube video, uploaded to the Internet by britishsnoring on Apr. 26, 2010, <http://www.youtube.com/watch?v=OXfN76M2I1A>.
 Wearing your Jaw Dynasplint® System, YouTube video, uploaded to the Internet by dynasplint on Oct. 5, 2011, <http://www.youtube.com/watch?v=3hjP24aByd4>.
 "Tired of Your CPAP?", Houston Chronicle, Jan. 16, 2011.
 PCT, "Invitation to Pay Additional Fees and, Where Applicable, Protest Fee", and extra sheets, mailed Jul. 25, 2012 from the European Patent Office acting as International Searching Authority. PCT/US2012/036474 International Search Report, 6 pages, Sep. 9, 2012.
 PCT/US2012/036474 Written Opinion of the International Searching Authority, 12 pages, Sep. 9, 2012.
 FDA 510(k) Summary K061688, Sep. 8, 2006.
 FDA 510(k) Summary K962516, Sep. 10, 1996.
 FDA 510(k) Summary K033822, Feb. 6, 2004.
 FDA 510(k) Summary K033823, Feb. 6, 2004.
 FDA 510(k) Summary K972061, Aug. 21, 1997.
 FDA 510(k) Summary K042161, Oct. 27, 2004.
 Bailey, Premarket Notification [510(k)]Summary K013049 for mandibular repositioning appliance (device) known as NORAD(TM), clearance granted by United States FDA, Nov. 29, 2001.
 Bailey, Premarket Notification [510(k)] Summary K020893 for mandibular repositioning appliance (device) known as NORAD(TM), clearance granted by United States FDA, May 28, 2002.
 Ranir, LLC, 510(k) Summary K1021118 for Intraoral Anti-Snoring Device known as Snore Guard Advance(TM), clearance granted by United States FDA, Sep. 8, 2010.
 Sybron Dental Specialties, 510(k) Summary K070327 for Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea known as Removable Acrylic Herbst(TM), Alleece Snore Appliance(TM), and Enoch Snorinator(TM), clearance granted by United States FDA, May 25, 2007.
 Hoffstein, "Review of oral appliances for treatment of sleep-disordered breathing", Sleep Breath (2007) 11:1-22, published online Nov. 29, 2006, Springer-Verlag.
 Pancer et al., "Evaluation of Variable Mandibular Advancement Appliance for Treatment of Snoring and Sleep Apnea", Chest (1999); 116:1511-1518.
 Randerath et al., "Non-CPAP therapies in obstructive sleep apnoea", Eur Respir J (2011);37: 1000-1028.

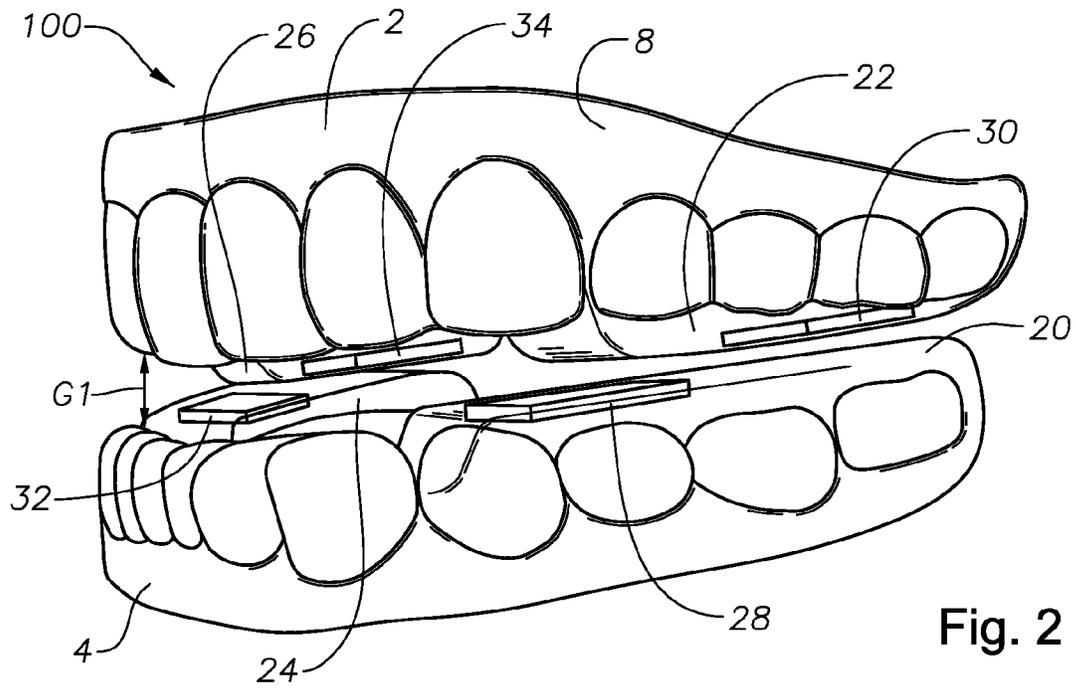


Fig. 2

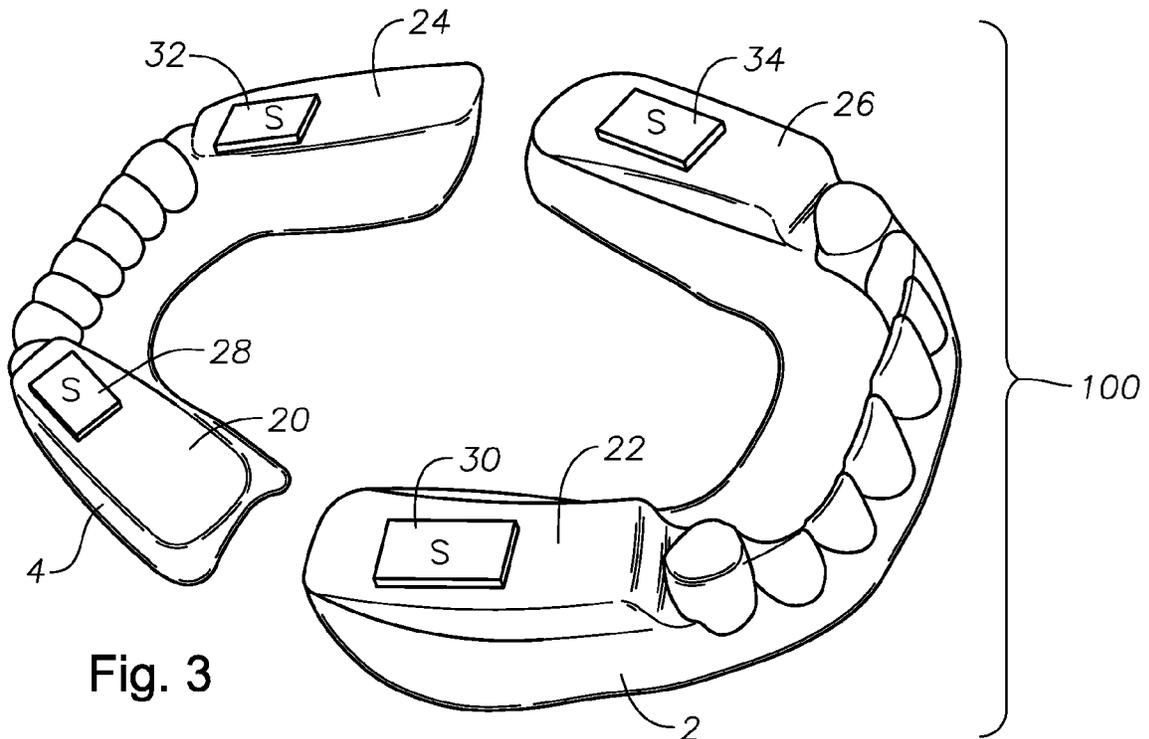


Fig. 3

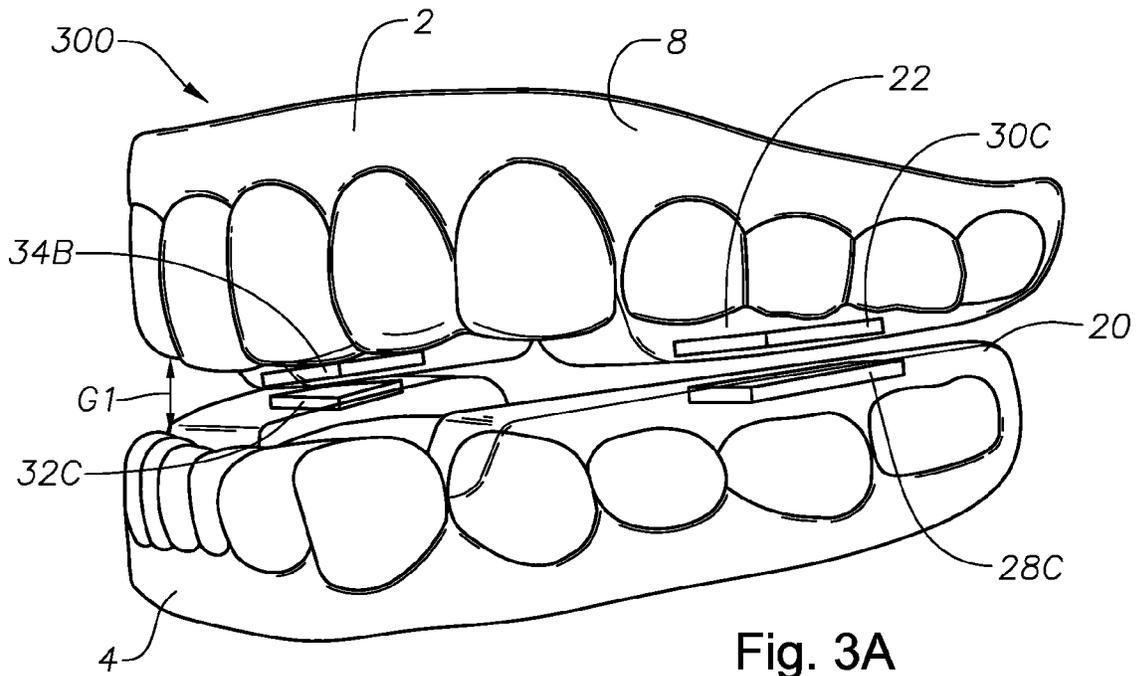


Fig. 3A

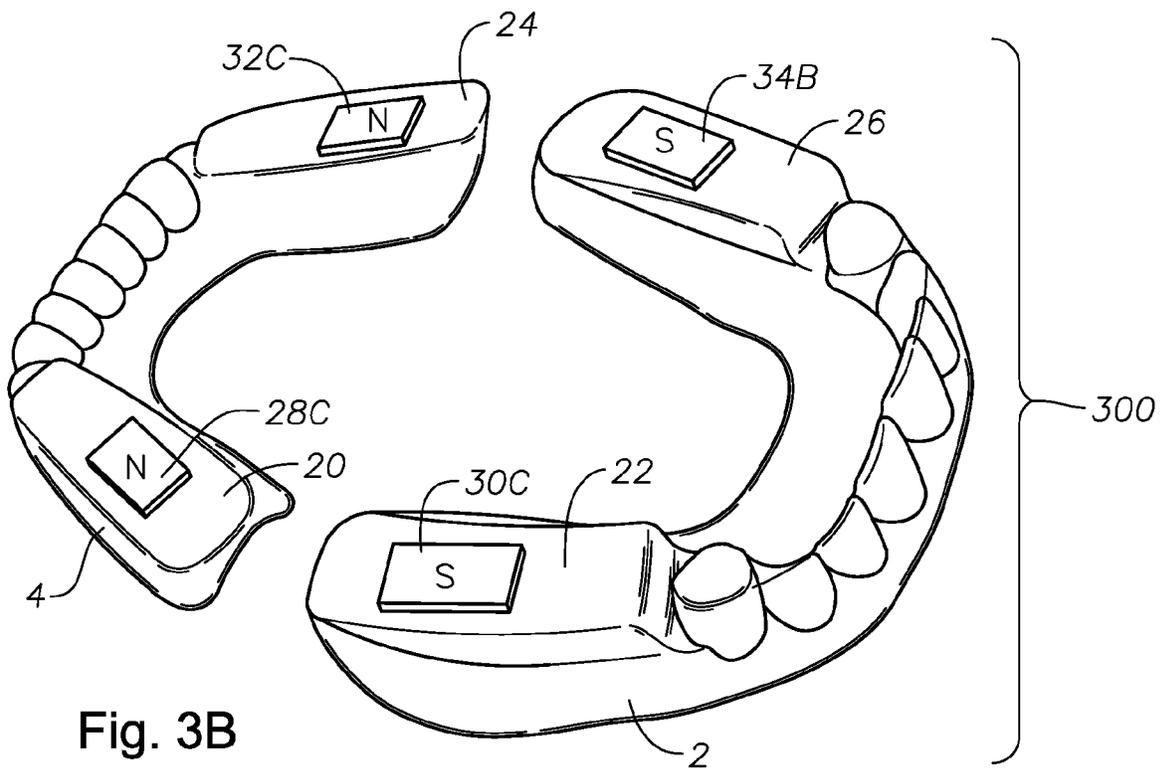


Fig. 3B

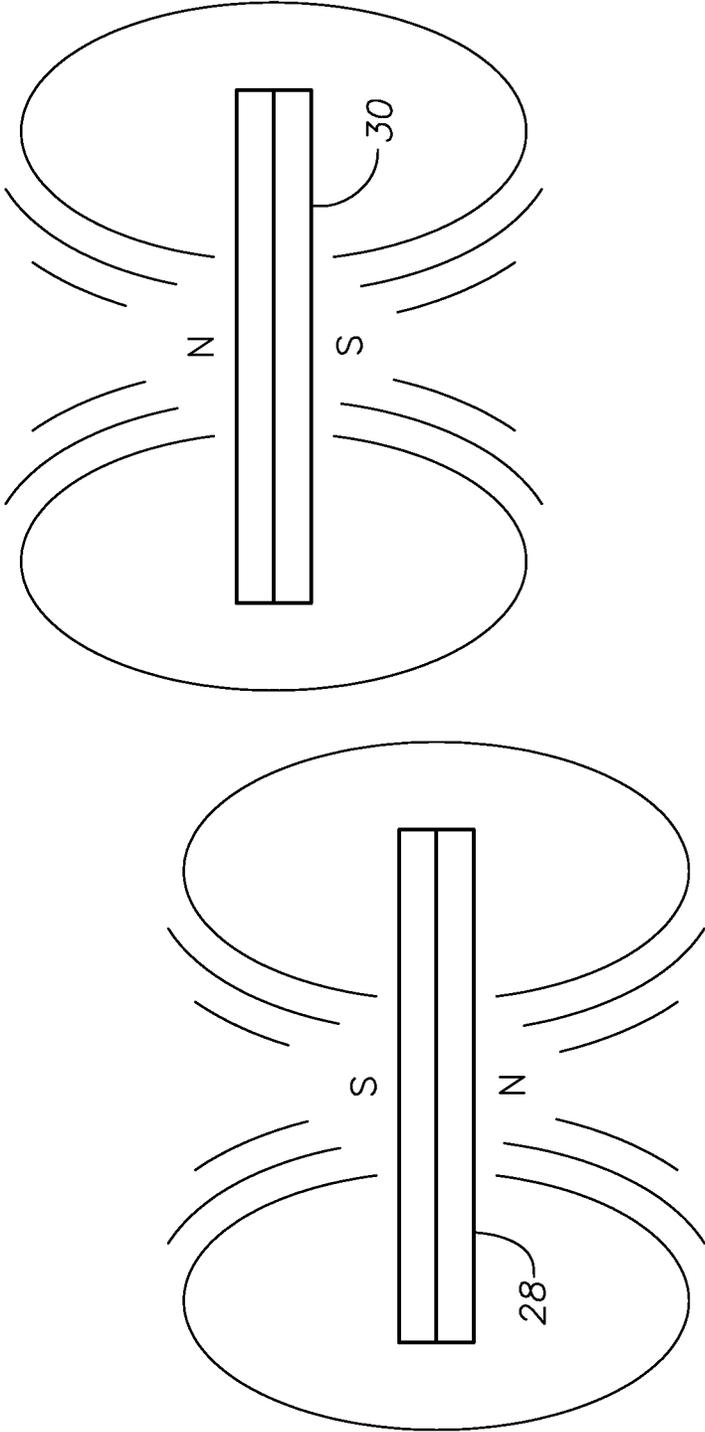
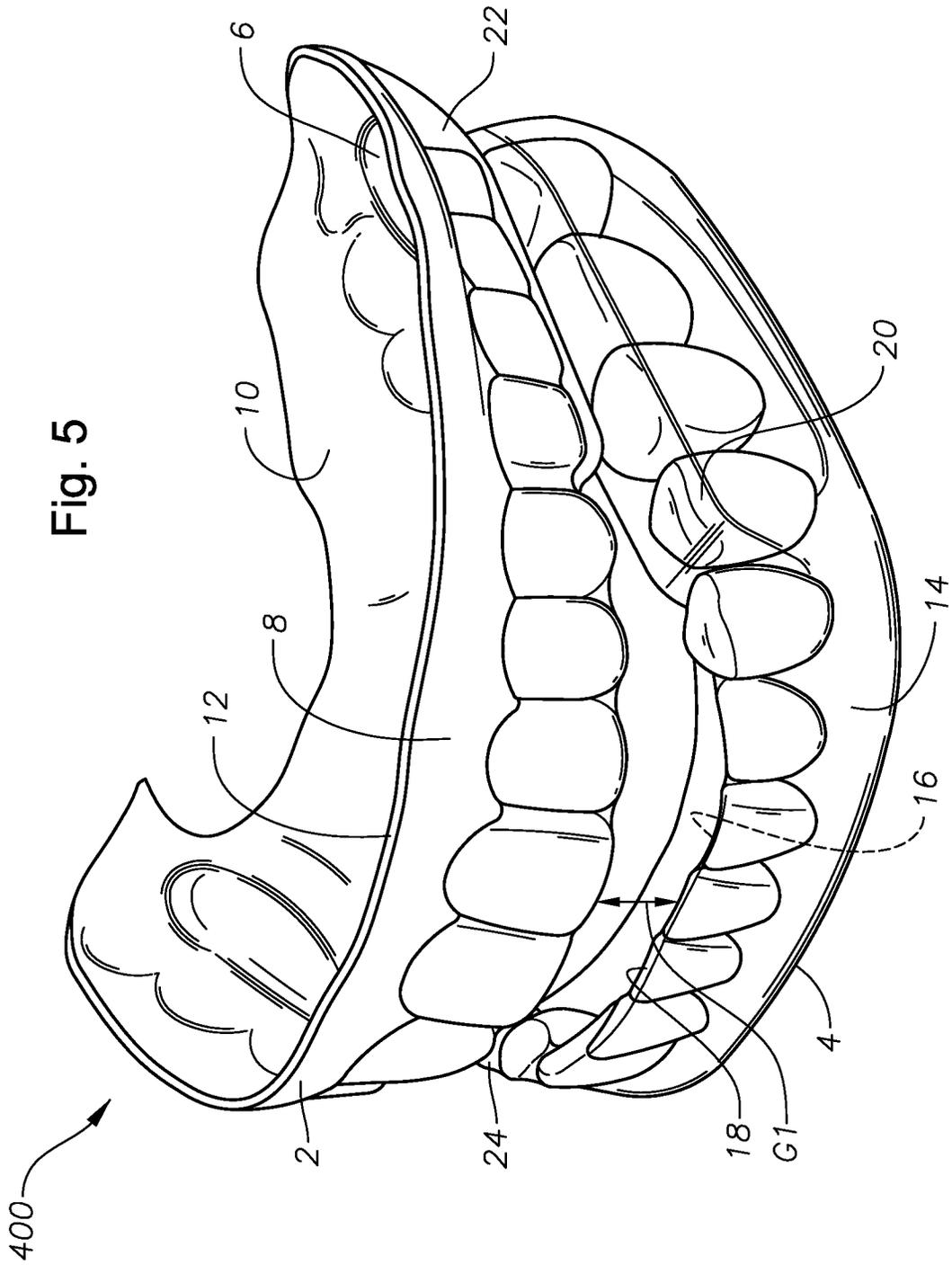
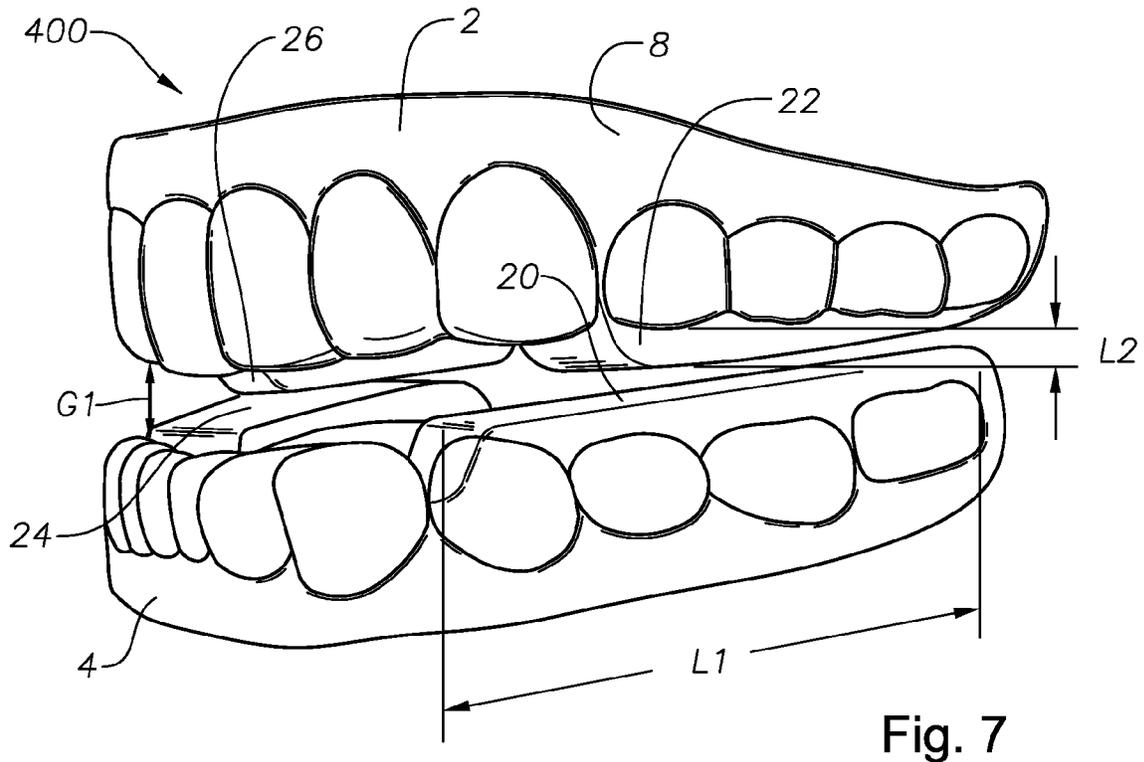
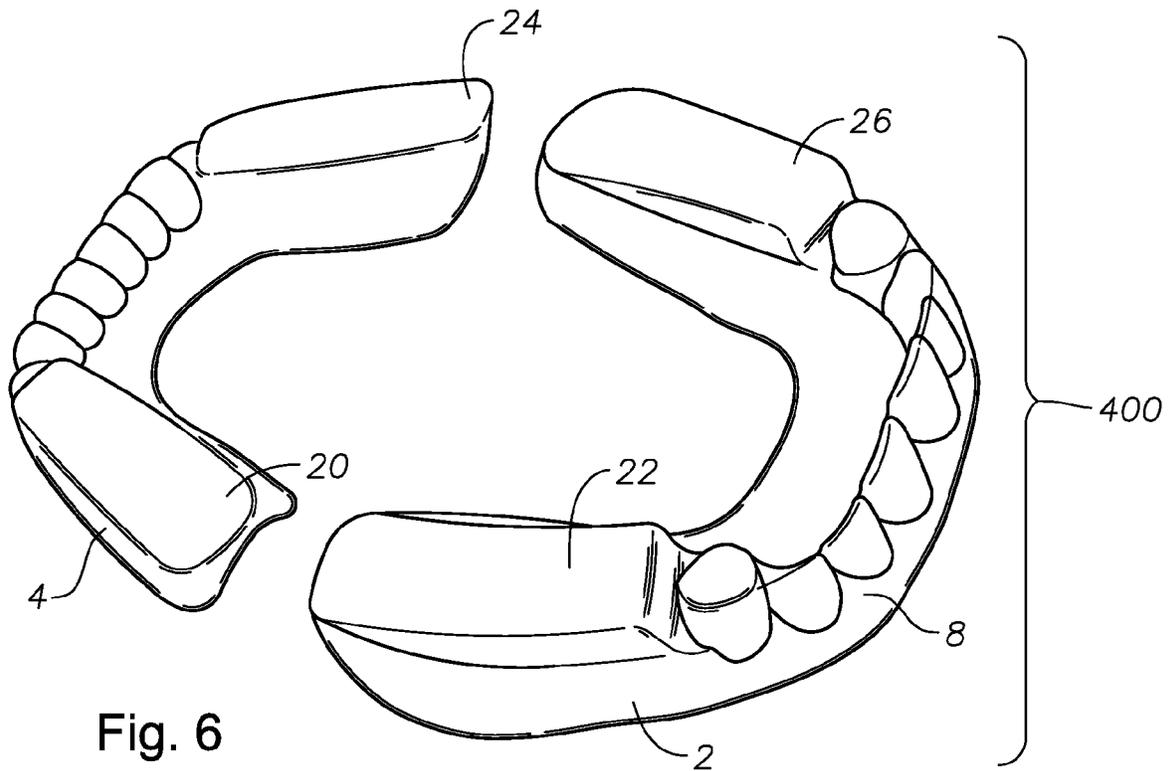
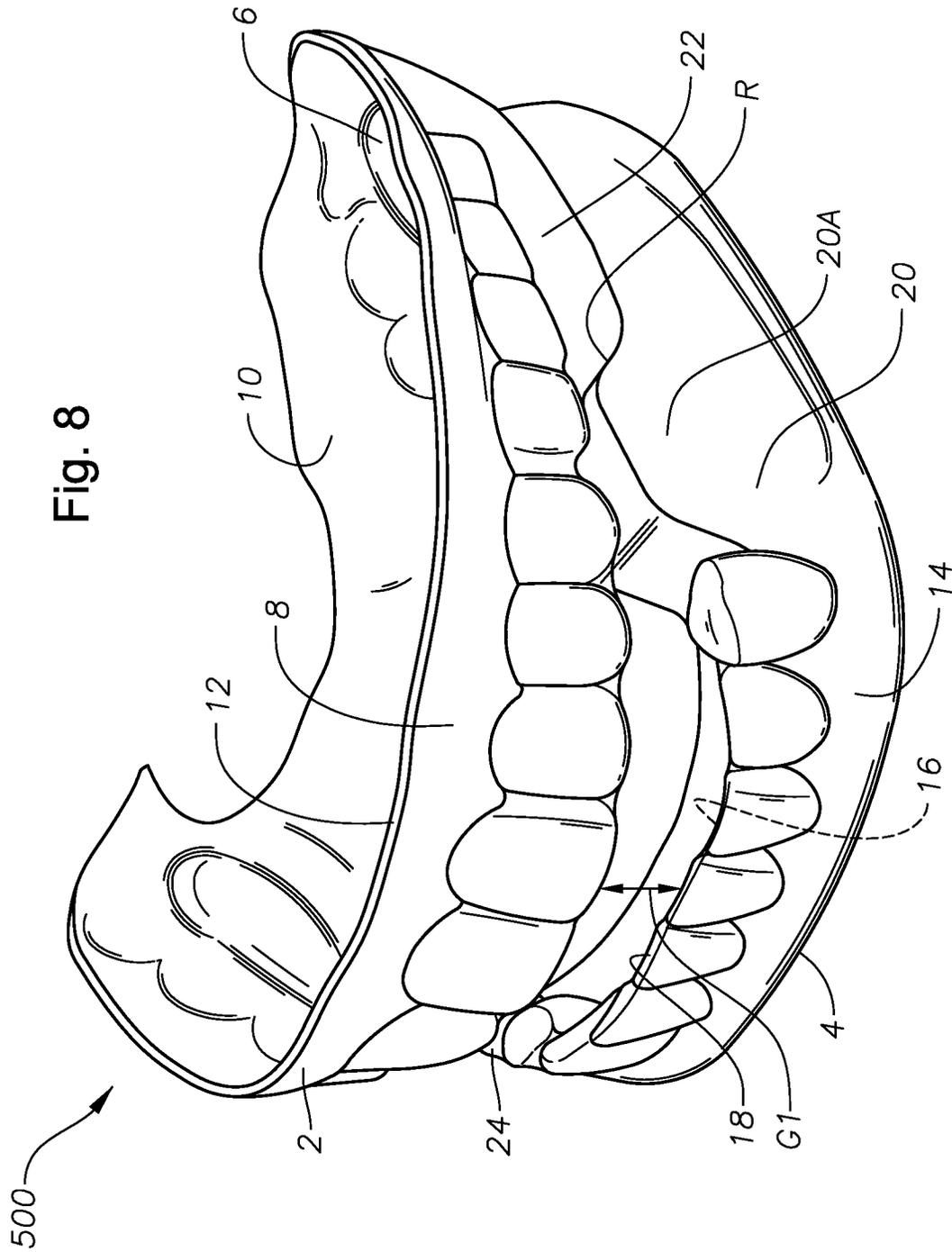


Fig. 4







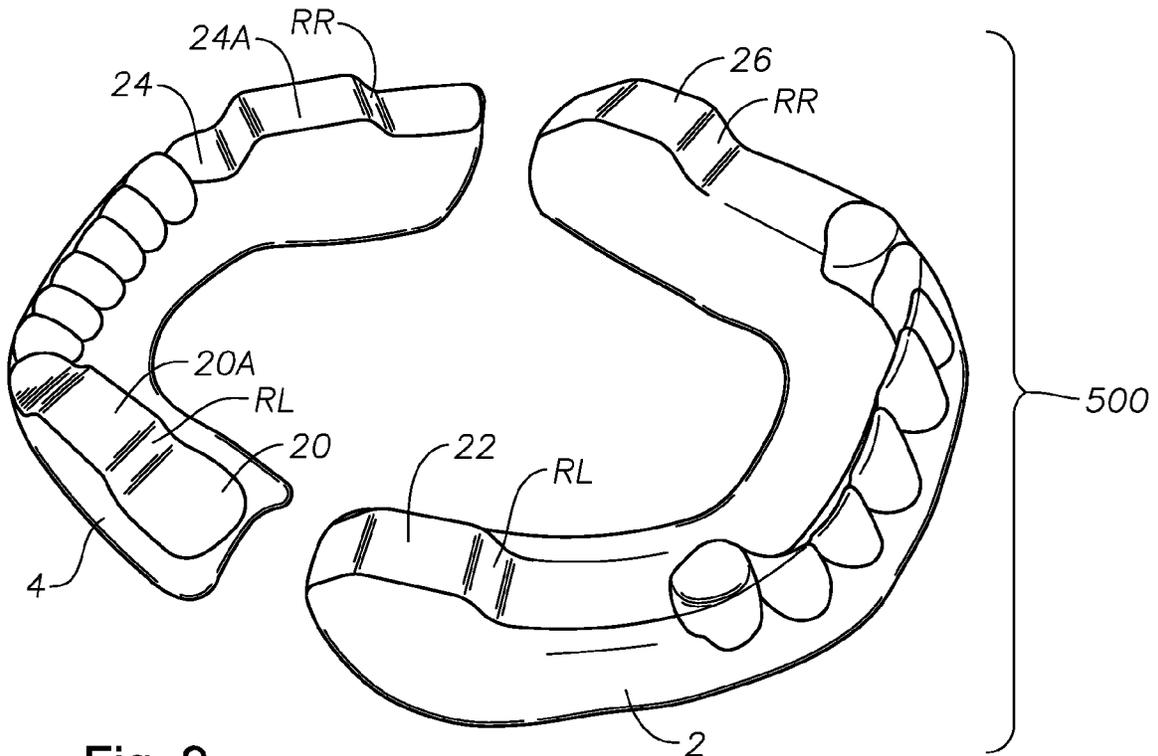


Fig. 9

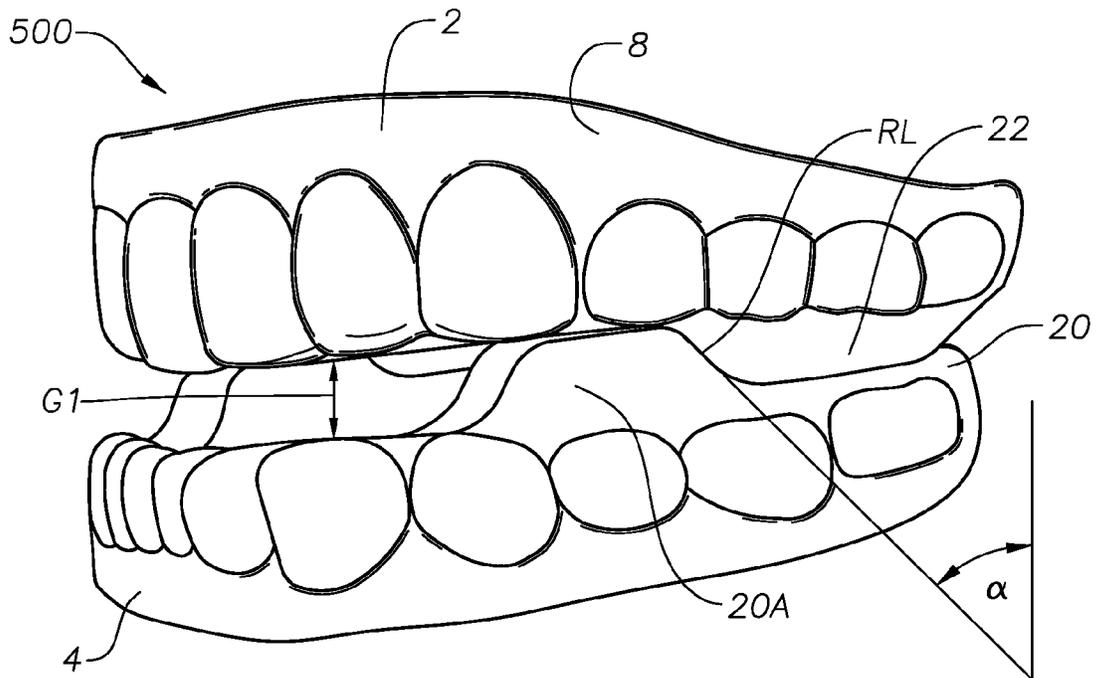


Fig. 10

1

ORAL DEVICES, KITS AND METHODS FOR REDUCING SLEEP APNEA, SNORING, AND/OR NASAL DRAINAGE

BACKGROUND INFORMATION

1. Technical Field

The present disclosure relates to oral devices, apparatus, kits, and methods for reducing or eliminating obstructive sleep apnea, snoring and/or nasal drainage in mammals.

2. Background Art

Sleep apnea is a reduction in the blood oxygen level due to any cause. The present disclosure relates to “obstructive sleep apnea”, which is problematic for many people—about 12 to 18 million people in the United States as of 2008. Obstructive sleep apnea (OSA) involves a reduction in breathing, called hypopneas, or a complete halt in airflow, called apneas, during sleep. Most pauses last 10 to 30 seconds, but some may persist for one minute or longer, according to the American Academy of Sleep Medicine. See Landers, S J, “*Link strengthened between sleep apnea and mortality risk*”, *amednews*, Sep. 1, 2008. As indicated in this article, apnea has been linked to higher mortality risks.

There are of course many known devices which claim to reduce or eliminate OSA, and these devices typically fall in two categories: external masks, such as the CPAP (continuous positive airway pressure) masks; and oral devices, sometimes referred to as mandibular splints. Pharmaceuticals comprise another category. The present disclosure involves the oral device or mandibular splint category.

Another discomfort is nasal or sinus drainage, sometimes referred to as nasal or sinus congestion, nasal or sinus drip, nasal or sinus irritation. The term “nasal drainage” is used herein to include all of these conditions unless otherwise noted. Non-oral products, such as adhesive strips positioned on the nose, may relieve some of these symptoms. However, nasal strips may only reduce anterior (frontal) congestion, and not posterior (throat) congestion.

Many of the known oral devices are uncomfortable and/or complicated, leading to reduced use. Furthermore, their use in humans may reduce speaking substantially, or at least the ability to speak understandably. A long felt and unmet need remains for an oral device, apparatus or kit, and methods of using these, to efficiently, safely and comfortably reduce or prevent OSA, snoring, and/or nasal drainage.

SUMMARY

In accordance with the present disclosure, oral devices, apparatus and kits are presented, as well as methods of using same, which reduce or overcome one or more of the problems of obstructive sleep apnea, snoring and other loss of sleep issues, and/or nasal drainage.

A first aspect of the disclosure is an apparatus (the words “apparatus” and “oral device” are used interchangeably herein) comprising:

an upper generally arched-shaped member that is configured to fit adjacent at least a portion of interior and exterior surfaces of a user’s upper dentition, the upper generally arched-shaped member comprising a moldable polymeric material;

a lower generally arched-shaped member of the same moldable polymeric material that is configured to fit adjacent at least a portion of interior and exterior surfaces of a user’s lower dentition;

the lower generally arch-shaped member comprising an anterior lower right molar extension and an anterior

2

lower left molar extension of the same moldable polymeric material, the anterior lower right and the anterior lower left molar extensions formed integrally with and projecting generally perpendicularly away from the lower generally arch-shaped member and generally toward the upper generally arch-shaped member;

the upper generally arch-shaped member comprising a posterior upper right molar extension and a posterior upper left molar extension of the same moldable polymeric material, the posterior upper right and posterior upper left molar extensions formed integrally with and projecting generally perpendicularly away from the upper generally arch-shaped member and generally toward the lower generally arch-shaped member;

so that when the user bites or clenches, the posterior right and left upper molar extensions impinge on the lower generally arch-shaped member, and the anterior right and left lower molar extensions impinge on the upper generally arch-shaped member;

the upper and lower generally arch-shaped members having an anterior shape to form a gap sufficient for at least a portion of the user’s tongue to extend forward into the gap without being impeded in forward movement by the apparatus;

the apparatus comprising left and right angled ramps; the left angled ramp being between a tapered portion of the posterior upper left molar extension and a matching tapered portion of the anterior lower left molar extension;

the right angled ramp being between a tapered portion of the posterior upper right molar extension and a matching tapered portion of the anterior lower right molar extension;

the ramps configured such that, when the apparatus is in a user’s mouth, the ramps create a tendency for the lower generally arch-shaped member, lower dentition and mandible to move downward as they move back toward the user’s throat, tending to keep a user’s airway open by maintaining the gap.

Any of the apparatus described herein may be part of a kit comprising one or both upper and lower generally arch-shaped members substantially as described herein, in certain embodiments packaged in a carrying case.

A second aspect of the disclosure is a method comprising: a) inserting the upper and lower generally arch-shaped members into a users mouth and onto the upper and lower dentitions; and

b) wearing both of the upper and lower generally arch-shaped members for a time sufficient to reduce one or more conditions selected from the group consisting of sleep apnea, snoring, and nasal drainage.

Certain methods may comprise adjusting one or both arch-shaped members to comfortably fit the user’s upper and/or lower dentitions.

Further aspects and advantages of apparatus and methods of the present disclosure will become apparent by reviewing the detailed description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1, 2, and 3 are various views of one apparatus or kit embodiment within the present disclosure;

FIGS. 2A and 2B are views of another apparatus or kit embodiment within the present disclosure;

FIGS. 3B and 3B are views of another apparatus or kit embodiment within the present disclosure;

3

FIG. 4 is a schematic side elevation view of an arrangement of magnets useful in the apparatus or kit illustrated schematically in FIGS. 1-3;

FIGS. 5, 6, and 7 illustrate schematically various views of another apparatus or kit embodiment in accordance with the present disclosure; and

FIGS. 8, 9, and 10 illustrate schematically various views of another apparatus or kit embodiment in accordance with the present disclosure.

It is to be noted, however, that the appended drawings are not to scale and illustrate only typical embodiments of this disclosure, and are therefore not to be considered limiting of its scope, for the apparatus, kits, and methods of the disclosure may admit to other equally effective embodiments. Identical reference numerals are used throughout the several views for like or similar elements.

DETAILED DESCRIPTION

In the following description, numerous details are set forth to provide an understanding of the disclosed oral devices, kits and methods of their use. However, it will be understood by those skilled in the art that the oral devices, kits, and methods covered by the claims may be practiced without these details and that numerous variations or modifications from the specifically described embodiments may be possible and are deemed within the claims. All U.S. published patent applications and U.S. Patents referenced herein are hereby explicitly incorporated herein by reference. In the event definitions of terms in the referenced patents and applications conflict with how those terms are defined in the present application, the definitions for those terms that are provided in the present application shall be deemed controlling.

As used herein the phrase “generally arched-shaped” means the shape of a member resembles an arch in the same way that the upper and lower teeth of a user resemble arches. The phrase “adjacent at least a portion of interior and exterior surfaces”, as that term is used herein when referring to the generally arch-shaped members, means that the generally arch-shaped members are adjacent to and touching at least one surface of the upper or lower teeth concerned, but some “looseness” is allowed, so that the members may move away from the teeth slightly, for example if the material of the member stretches or deforms, such as during insertion into or removal from the mouth. As used herein the term “user” means a human or other mammal that employs an apparatus of this disclosure in its mouth. The term “subject” may also be used and is considered interchangeable with the term “user.”

The present disclosure relates generally to apparatus, kits, and methods for reducing or eliminating sleep and other disorders, and more specifically to apparatus for reducing or eliminating obstructive sleep apnea (OSA), snoring, and/or nasal drainage. A particular use for apparatus and kits of this disclosure is for humans, but they may also be used for other mammals. Certain embodiments may also be used as athletic mouth guards for upper, lower, or both dentitions.

In certain embodiments, the gap (denoted G1 in the various figures) may have a distance ranging from about 1 to about 20 mm, or from about 5 to about 15 mm.

The lateral length (L1 in FIG. 7) of the upper and lower molar extensions, i.e., the distance along the molar teeth, may be 10 mm or more, or may range from 10 to about 50 mm or from about 12 to about 24 mm. In certain embodiments having an offset, the length of the upper and the lower molar extensions may each be about one half of these

4

lengths. In certain embodiments, a goal is to keep the upper and lower molar extensions as short as possible to maintain the gap as large as possible.

In certain embodiments the molar extensions may have a vertical length (L2 in FIG. 7) of 20 mm or less, in certain embodiments 16 mm or less. The average vertical distance of upper and lower molar extensions in non-offset embodiments is about 10 mm (5 mm for upper, 5 mm for lower molar extensions). In certain embodiments that may have an “offset”, such as may be provided by left and right-side ramps as illustrated in FIGS. 8, 9, and 10, the upper or lower molar extensions may comprise the entire vertical length (i.e., all 10 mm may in certain embodiments be in the upper molar extensions; in certain other embodiments the entire 10 mm may be in the lower molar extensions). In certain embodiments within the first aspect the upper generally arch-shaped member comprises two upper molar extensions, one extending from a right-side upper molar region, and the second extending from a left-side upper molar region. Similarly, in certain embodiments within the second aspect the upper generally arch-shaped member comprises two lower molar extensions, one extending from a right-side lower molar region, and the second extending from a left-side lower molar region.

In certain embodiments the upper and lower members each may comprise a moldable material selected from the group consisting of synthetic and natural materials. Synthetic materials may be selected from the group consisting of polymeric materials, as further discussed herein. In certain apparatus the arch-shaped members and the molar extensions comprise a polymeric material.

In certain embodiments, each molar extension may comprise at least one magnet. In certain embodiments the magnets are embedded in the polymeric material of the molar extensions. In certain embodiments, an upper right magnet has polarity opposite that of a lower right magnet, and an upper left magnet has a polarity opposite that of a lower left magnet. In certain embodiments, the magnets may be flat shaped and embedded into the plastic of the molar extensions. In certain embodiments, such as illustrated in FIG. 4, the flat-shaped magnets may have a north pole on one of their major surfaces and a south pole on its other major surface.

Referring to FIGS. 1 and 2, there is illustrated schematically a perspective view of one apparatus 100 in accordance with the disclosure. Apparatus embodiment 100 includes an upper generally arch-shaped member 2 and a lower generally arch-shaped member 4. Upper generally arch-shaped member 2 includes an exterior wall 8 and an interior wall 10, custom-shaped for the user's upper dentition, and which together define a trough 6 for friction fitting adjacent the upper dentition of a user. An upper connecting portion 12 connects exterior wall 8 and interior wall 10. Connecting portion 12 may be rather thin or pointed in the area of the front teeth, and rather flat or planar in the area of the back molar teeth. Similarly, lower generally arch-shaped member 4 includes an exterior wall 14, and an interior wall 16, the latter being mostly hidden in the views of FIGS. 1 and 2. A lower connecting portion 18 connects walls 14 and 16, and as with upper connecting portion 12, lower connecting portion 18 may be rather thin or pointed near the front teeth of the user, and rather flat or planar near the lower molars of the user.

As perhaps more clearly viewed in FIG. 2, embodiment 100 includes a lower left molar extension 20 and an upper left molar extension 22, each extending generally perpendicularly away from their respective members. FIG. 3 illus-

5

trates schematically upper generally arch-shaped member 2 in a 180 degree flip from its "in use" position to more clearly illustrate a lower right molar extension 24 and an upper right molar extension 26. FIG. 3 also allows viewing of flat-shaped magnets 28, 30, 32 and 34 fully embedded in their respective molar extensions. Members 2 and 4, as well as molar extensions 20, 22, 24, and 26 comprise the same moldable polymeric material in this embodiment.

As generally may be seen in FIGS. 2 and 3, and more specifically illustrated in the schematic diagrams in FIG. 4, magnets 28 and 30 have, in this embodiment, a specific spatial relationship. The respective north and south poles of these magnets are arranged so that when placed as viewed in FIG. 4, they will substantially repel one another by virtue of their respective magnetic field lines being unable to cross, forcing the mandible down and forward. Magnets 32, 34 may have the same spatial and magnetic relationship. As this occurs, embodiment 100 will tend to keep a user's airway open by creating a gap between upper portion 2 and lower portion 4, near the front teeth, as indicated by double-headed arrow G1 in FIGS. 1 and 2.

FIGS. 2A and 2B are views of another apparatus or kit embodiment 200 within the present disclosure. In embodiment 200, magnets 28A, 28B, 30A, 32A, 32B, and 34A are all embedded in their respective molar extensions. In embodiment 200, magnet 28A has a south pole facing away from left lower molar extension 20, and a north pole facing left lower molar extension 20. Magnet 28B has a south pole facing left lower molar extension 20, and a north pole facing away from left lower molar extension 20. Also in embodiment 200, magnet 32A has a south pole facing away from right lower molar extension 24, and a north pole facing right lower molar extension 24. Magnet 32B has a south pole facing right lower molar extension 24, and a north pole facing away from right upper molar extension 24. Magnet 34A has a south pole facing away from right upper molar extension 26, and a north pole facing toward right upper molar extension 26. Magnet 30A has a south pole facing away from left upper molar extension 22, and a north pole facing toward left upper molar extension 22. It is noted that the magnetic poles of each magnet could be reversed to arrive at substantially the same embodiment. In both embodiment 200 and its "reverse" poles sister embodiment, there will be magnetic attraction between magnets 28B and 30A, as well as between magnets 32B and 34A, while there will be a slight magnetic repulsion between magnets 32A and 34A, as well as between magnets 28A and 30A. In this embodiment and others like it, the magnetic attraction and repulsion thus may be adjusted depending on the particular user, for example the strength of the user's jaw muscles.

FIGS. 3A and 3B are views of another apparatus or kit embodiment 300 within the present disclosure. In embodiment 300, magnets 28C, 30C, 32C, and 34B are all embedded in their respective molar extensions. In embodiment 300, magnet 28C has a south pole facing toward left lower molar extension 20, and a north pole facing away from left lower molar extension 20. Magnet 32C has a south pole facing right lower molar extension 24, and a north pole facing away from right lower molar extension 24. Also in embodiment 300, magnet 30C has a south pole facing away from left upper molar extension 22, and a north pole facing left upper molar extension 22. Magnet 34B has a south pole facing away from right upper molar extension 26, and a north pole facing right upper molar extension 26. Magnet 34C has a south pole facing away from right upper molar extension 26, and a north pole facing right upper molar extension 26. It is noted that the magnetic poles of each

6

magnet could be reversed to arrive at substantially the same embodiment. In both embodiment 300 and its "reverse" poles sister embodiment, there will be magnetic attraction between magnets 28C and 30C, as well as between magnets 32C and 34B. In this embodiment and others like it, the magnetic attractions may be adjusted depending on the particular user, for example the strength of the user's jaw muscles, by adjusting the strength of the magnets.

FIGS. 5, 6, and 7 illustrate schematically various views of another apparatus embodiment 400 in accordance with the present disclosure, which is the same as embodiment 100 but without magnets. FIG. 7 illustrates lengths L1 and L2, as well as gap G1.

FIGS. 8, 9, and 10 illustrate schematically various views of another apparatus or kit embodiment 500 in accordance with the present disclosure, illustrating an offset or ramp R between upper portion 2 and lower portion 4 created by a left ramp area (RL) and a right ramp area (RR). A tapered lower anterior left molar extension 20A may slidably move adjacent a matching tapered upper posterior left molar extension 22 in the area of left ramp area RL, where faces of components 20A and 22 may slide against each other at an angle α (FIG. 10). Similarly on the right side, a tapered lower anterior right molar extension 24A may slidably move adjacent a matching tapered upper posterior right molar extension 26 (not viewable in FIGS. 8 and 10, but illustrated in exploded view of FIG. 9). Ramps RL and RR create a tendency for the lower portion 4 to move downward as lower portion 4 moves back toward the user's throat. Movement of the lower jaw backwards is a natural movement during sleep. As this occurs, embodiment 500 will tend to keep the airway open by creating a gap between upper portion 2 and lower portion 4, near the front teeth, as indicated by double-headed arrow G1 in FIG. 1. This gap may be important in methods of reducing nasal drainage, perhaps more important than forward movement of the lower jaw.

The materials of construction of the upper and lower members may comprise any moldable plastic (polymeric) material that is approved for use in oral medical devices and appliances for human use and that may be custom fitted for each user and tooth-retained via friction grip, and materials approved for animal use. The members may comprise a single material, or combination of materials. The members may comprise more than one layer of material, and each layer may be the same or different. The polymeric materials may be filled with various fillers, extenders, pigments, and other additives. Suitable polymeric materials include thermoplastics, thermosetting polymers, elastomers, and thermoplastic elastomers. The polymeric materials may comprise co-polymers, ter-polymers, and blends of two or more chemical types of polymers, or blends of two or more polymers of the same chemical type, for example, a blend of two thermoplastics having different molecular weights.

Examples of specific polymers include polyacrylics, polyvinyls, polyvinyl alcohols, and the like. An example of a suitable polymeric material is a durable fade-proof acrylic that retains its shape and color for at least four-five years. Another example is made of a very pliable, soft, custom-injected silicone. Another example is a polymeric material compatible with home/office based bleaching techniques, such as the material used to make an OSAP device, and materials that can be molded into a ready-made semi-universal trial version, which may be suitable for patients who cannot endure having their impressions taken. In addition, the trial version is an inexpensive way to test a particular patients' tolerance to oral therapy. Another example is the material used in the device known under the

trade designation SAGA. This device consists of a hard acrylic shell laminated to a soft vinyl liner. Another example is the acrylic material (Bruxeze™) that softens in hot water to provide a combination of comfort, strength, and retention, and which is used in the Adjustable PM Positioner™, an appliance that fits over all maxillary and mandibular teeth. Another example are the materials used in the device known as SomnoGuard® AP, which consists of an upper and a lower tray each made of two materials. The outer tray shells consist of solid clear and transparent medical grade polycarbonate. The inner lining which accommodates the teeth impressions is made of a thermoplastic copolymer. After the oral appliance is heated in a hot water bath its thermoplastic body molds easily to the teeth and jaws allowing any medical doctor to fit the device chair side. Yet another example is the material employed in the device known as SomnoGuard AP Pro®, which is a dental lab made two-part mandibular adjustable positioner to treat snoring and mild to moderate sleep apnea, and comprises common acrylic/elastic/thermoform dental materials available in any dental lab after taking impressions of the lower and upper jaws and producing plaster models. Other polymeric materials that may be useful include nitinol, silicone, a PET, or any other biocompatible polymeric material. Other possible examples include PTFE, e-PTFE, polypropylene, polyurethane, polycarbonate, polyethylene terephthalate, stainless steel, titanium, tantalum, gold, polyvinidylene fluoride and combinations thereof.

The molar extensions may either be molded using special molds, or built up by applying a paste or solution of polymeric precursor materials and swabbing the precursors materials on the appropriate areas. In certain embodiments, this may need to be done repeatedly to build up the molar extension to functional length.

Magnets which may be useful in apparatus of this disclosure include rare earth magnets, such as samarium-cobalt and neodymium-iron-boron magnets. It has become possible to produce magnets with small enough dimensions for dental applications and yet still provide the necessary forces. Certain embodiments may employ magnets of the “closed field” type. In this type of system, a soft magnetic or ferromagnetic material, such as ferritic or martensitic stainless steel or Pd—Co—Ni alloy, is implanted into the jaw, rather than a magnet, to provide attractive force to hold the denture in place. This implant is known as a “keeper”. In this configuration, the magnetic field lines are shunted through the keeper as it is the path of minimum energy and there is no magnetic field experienced in the oral cavity. U.S. Pat. Nos. 6,659,771, 5,678,998, 5,013,243 and 6,299,450 describe small yet powerful magnets for cooperating with a non-magnet implanted “keeper” for denture attachment. The non-magnet keeper is made of a magnet-attracted material, such as a soft magnetic or ferromagnetic material, but is not a permanent magnet. U.S. Pat. No. 4,396,373 describes a removable orthodontic appliance having two permanent magnets carried by two caps, respectively, having facing poles which are in registry when the mouth is normally closed, exerting a magnetic force in a direction substantially normal to the occlusal plane. The opposing magnets have confronting poles with like-polarity such that the magnets repel and develop intrusive forces upon the respective teeth. U.S. Pat. No. 4,671,767 discloses both fixed and removable orthodontic devices that use magnets. The magnets are secured to removable or fixed orthodontic devices and are positioned bilaterally in the posterior molar regions. The faces of the magnets are oriented such that they repel each

other, thereby creating magnetic forces parallel to the occlusal plane for urging the mandible forward.

According to U.S. Pat. No. 7,712,468, which discloses a removable magnetic dental appliance, the magnetic orthodontic devices described above employ “open field” magnetic configurations, which are potentially harmful to the local tissues in the oral cavity, especially since the devices are designed for long-term use. Furthermore, the appliances are uncomfortable to wear.

Any of the magnets discussed in these patent and publications would be useable in apparatus and kits disclosed herein.

If desired, fastening means may be employed to fasten one or more of the members in the users mouth. Hook and loop fasteners are common and require no further explanation. One preferred hook and loop fastener is that known under the trade designation Velcro®, available from Velcro USA, Manchester, N.H.

Although the foregoing description is intended to be representative of apparatus, kits, and methods in accordance with the present disclosure, it is not intended to in any way limit the scope of the appended claims.

What is claimed is:

1. An apparatus comprising:

- an upper generally arched-shaped member that is configured to fit adjacent at least a portion of interior and exterior surfaces of a user’s upper dentition, the upper generally arched-shaped member comprising a moldable polymeric material;
- a lower generally arched-shaped member of the same moldable polymeric material that is configured to fit adjacent at least a portion of interior and exterior surfaces of the user’s lower dentition;
- the lower generally arch-shaped member comprising an anterior lower right molar extension and an anterior lower left molar extension of the same moldable polymeric material, the anterior lower right and the anterior lower left molar extensions formed integrally with and projecting generally perpendicularly away from the lower generally arch-shaped member and generally toward the upper generally arch-shaped member;
- the upper generally arch-shaped member comprising a posterior upper right molar extension and a posterior upper left molar extension of the same moldable polymeric material, the posterior upper right and posterior upper left molar extensions formed integrally with and projecting generally perpendicularly away from the upper generally arch-shaped member and generally toward the lower generally arch-shaped member;
- so that when the user bites or clenches, the posterior right and left upper molar extensions impinge on the lower generally arch-shaped member, and the anterior right and left lower molar extensions impinge on the upper generally arch-shaped member;
- the upper and lower generally arch-shaped members having an anterior shape to form a gap sufficient for at least a portion of the user’s tongue to extend forward into the gap without being impeded in forward movement by the apparatus;
- the apparatus comprising left and right angled ramps;
- the left angled ramp being between a tapered portion of the posterior upper left molar extension and a matching tapered portion of the anterior lower left molar extension;

9

the right angled ramp being between a tapered portion of the posterior upper right molar extension and a matching tapered portion of the anterior lower right molar extension;

the ramps configured such that, when the apparatus is in the user's mouth, the ramps create a tendency for the lower generally arch-shaped member, lower dentition and mandible to move downward as they move back toward the user's throat, tending to keep the user's airway open by maintaining the gap.

2. The apparatus of claim 1 wherein the gap ranges from about 5 to about 15 mm.

3. The apparatus of claim 1 wherein each molar extension has a lateral length of 10 mm or more.

4. The apparatus of claim 1 wherein the molar extensions each have a vertical height of 5 mm or less.

5. A kit comprising the upper and lower generally arch-shaped members of claim 1.

10

6. A method comprising:

- a) inserting the upper and lower generally arch-shaped members of claim 1 into the user's mouth and fitting the upper generally arch-shaped member adjacent at least the portion of the interior and exterior surfaces of the user's upper dentition, and fitting the lower generally arch-shaped member adjacent at least the portion of the interior and exterior surfaces of the lower dentition; and
- b) wearing the upper and lower generally arch-shaped members for a time sufficient to reduce one or more conditions selected from the group consisting of sleep apnea, snoring, and nasal drainage.

7. The method of claim 6 comprising adjusting the upper generally arch-shaped member to fit adjacent at least the portion of the interior and exterior surfaces of the user's upper dentition, adjusting the lower generally arch-shaped member to fit adjacent at least the portion of the interior and exterior surfaces of user's lower dentition, or adjusting both.

* * * * *